

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention****[30Day-22-1335]****Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) submitted the information collection request titled "CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 30, 2021, to obtain comments from the public and affected agencies. CDC received 20 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters
(OMB Control No. 0920-1335, Exp. 4/30/2022) - Extension -
National Center for Emerging Zoonotic and Infectious Diseases
(NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As the COVID-19 pandemic has unfolded, this information collection has evolved. CDC's COVID-19 regulatory requirements in the Framework for a Conditional Sailing Order (CSO) expired on January 15, 2022, at 12:01am EST. CDC is transitioning to a new COVID-19 risk-mitigation program for cruise ships operating in U.S. waters. Cruise ship operators will have the option to participate in this program at their discretion. This program will include recommendations and guidance for cruise ships to continue to operate in a way that provides a safer and healthier environment for crew, passengers, and communities.

Through the implementation of the CSO, CDC has identified best practices for controlling the spread of COVID-19 on cruise ships and has coordinated with cruise ship operators and other stakeholders to implement these measures. CDC remains committed to working with the cruise industry, state, territorial, and local health authorities, and seaport partners to continue to implement these measures.

Cruise ship operators choosing to participate in the CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters on a voluntary basis agree to follow all recommendations and guidance

issued by CDC as part of this program. These recommendations are aimed at further reducing the introduction and spread of SARS-CoV-2 onboard. CDC will work closely with cruise ships opting into the program and continue to monitor compliance with COVID-19 preventive measures and cases onboard these cruise ships through daily enhanced data collection and inspections.

Cruise lines that decide not to participate in CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters will receive a designation showing that CDC has neither reviewed nor confirmed the cruise ship operator's COVID-19 health and safety protocols. Additionally, these ships will be subject to other CDC orders and regulations to the same extent as other ships and conveyances subject to the jurisdiction of the United States.

The guidance and recommendations included in CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters are aligned with previous health and safety protocols under the CSO. As such, cruise ship operators who have resumed operations under the CSO will already be familiar with the components of the program, and operators who choose to participate in the program will be able to continue sailing with passengers without interruption.

This information collection request outlines the reporting and document retention requirements that are part of CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters. Note, many of the data collection elements included in CDC's COVID-19 Program for Cruise Ships are currently approved as part

of OMB Package 0920-1335 *Phased Approach to the Resumption of Cruise Ship Passenger Operations*, submitted on April 30, 2021.

CDC will provide cruise ship operators with information about the program and how to contact CDC to opt in or opt out of the program.

Opting into the COVID-19 Program for Cruise Ships

Cruise lines operating cruise ships in U.S. waters choosing to participate in this program ("opting in") are requested to notify the CDC in writing of their decision to opt in by February 18, 2022.

Cruise lines choosing to participate in this program will be required to follow all recommendations and guidance as a condition of their participation—i.e., they will not be able to pick and choose which recommendations they follow. Those opting in will continue to receive a color status for cruise ships operating in U.S. waters on CDC's Cruise Ship Color Status webpage.

Cruise lines with ships not currently in U.S. waters—but that are expecting to return to U.S. waters after February 18, 2022—are requested to contact CDC via email at least 28 days prior to their ships' arrival. Instructions on how to participate in the program will be provided.

Cruise lines that initially decide to participate in the program but then later decide not to participate should contact CDC via email for instructions.

Opting Out of the COVID-19 Program

Cruise lines operating in U.S. waters choosing not to participate in the program ("opting out") are requested to notify CDC in writing by February 18, 2022.

Cruise lines that do not notify CDC by 5:00 pm ET on February 18, 2022, will be considered to have opted out of this program. Cruise lines that decide to opt out will have any cruise ships operating in U.S. waters listed as "Gray" ships on CDC's Cruise Ship Color Status webpage. This designation means that CDC has neither reviewed nor confirmed the cruise ship operator's health and safety protocols. Additionally, these ships will be subject to other CDC orders and regulations to the same extent as other ships and conveyances subject to the jurisdiction of the United States.

Cruise lines that initially decide to opt out but later decide to opt into the program should contact CDC via email at least 28 days prior to the day they intend to join the program. Instructions on how to participate in the program will be provided.

Cruise Ship Vaccination Status Classification

Cruise lines that choose to participate in CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters must advise CDC of the vaccination status classification for each participating ship. This information will be included on CDC's Cruise Ship Color Status webpage.

As part of CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters, cruise ship vaccination status classifications are defined as:

- **Not Highly Vaccinated:** ships with less than 95% of passengers and 95% of crew who are fully vaccinated.
 - Cruise ship operators that select this vaccination status classification will be required to enforce mask use and physical distancing onboard according to CDC guidance.
- **Highly Vaccinated:** ships with at least 95% of passengers and 95% of crew who are fully vaccinated, but less than 95% of passengers and 95% of crew are up to date with their COVID-19 vaccines.
 - Cruise ship operators that select this vaccination status classification will be required to enforce mask use—but not physical distancing—onboard according to CDC guidance. These cruise ship operators may implement physical distancing policies at their discretion.
- **Vaccination Standard of Excellence:** ships with at least 95% of passengers (including children) and 95% of crew who are up to date with their COVID-19 vaccines.
 - Cruise ship operators that select this vaccination status classification will not be required to enforce mask use or physical distancing onboard. These cruise

ship operators may implement mask use and physical distancing policies at their discretion.

Ships adhering to the "Highly Vaccinated" or "Vaccination Standard of Excellence" classifications must maintain these thresholds for each voyage.

COVID-19 Response Plans

Cruise ship operators choosing to participate in CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters must have a COVID-19 response plan that includes the following components:

- Terminology and use of definitions that align with how CDC uses and defines the following terms: "confirmed COVID-19," "COVID-19-like illness," "close contact," "fully vaccinated for COVID-19," and "isolation" and "quarantine" (including timeframes for isolation and quarantine).
- Protocols for on board surveillance of passengers and crew with COVID-19 and COVID-19-like-illness.
- Protocols for training all crew on COVID-19 prevention, mitigation, and response activities.
- Protocols for on board isolation and quarantine, including how to increase capacity in case of an outbreak.
- Protocols for COVID-19 testing that aligns with CDC technical instructions.
- Protocols for onboard medical staffing—including number and type of staff—and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, face masks, personal protective equipment) for the infected

without the immediate need to rely on shoreside hospitalization.

- Procedures for disembarkation of passengers who test positive for COVID-19.
- Statement that the cruise ship operator has observed and will continue to observe all elements of its COVID-19 response plan including following the most current CDC recommendations and guidance for any public health actions related to COVID-19.

Surveillance and Reporting

For cruise ships that have chosen to participate in the program, CDC requires daily submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form", in lieu of submitting the Maritime Conveyance Cumulative Influenza/Influenza-Like Illness (ILI) Form for COVID-19-like illness and the Maritime Conveyance Illness or the Death Investigation Form for individual cases of COVID-19. This EDC Form will be used to conduct surveillance for COVID-19 on board cruise ships using cumulative reports of confirmed COVID-19 and COVID-19-like illness, which includes acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) clinical criteria. Data points for this form include number of travelers (passengers and crew) currently onboard; case counts and diagnostic testing data for COVID-19 and COVID-19-like Illness (CLI); screening testing of asymptomatic travelers, isolation

practices, and the percentage of travelers who are fully vaccinated.

Access to the online EDC form has been provided to cruise lines by the Cruise Lines International Association (CLIA) and/or CDC. Cruise lines that do not have access should contact CLIA or CDC.

To address industry concerns about the burden of daily EDC submission, CDC will add an option in the online form (i.e., a check box) to streamline reporting if no cases were identified or no testing was conducted for that day. Additionally, to reduce reporting burden for cruise ships, CDC will continue to submit aggregate data to seaport authorities, state, local, and territorial health departments that oversee seaports, federal partners, and international maritime public health agencies.

The data collected in the EDC form are used to inform CDC's COVID-19 Color-Coding System for Cruise Ships. These data will greatly increase the transparency of the overall health of the crew members and passengers, and better allow the CDC to manage potential outbreaks and offer recommendations to the ship and port partners.

The color-coding system is only applicable to cruise ships that meet one of the following criteria:

1. Foreign-flagged cruise ships currently operating in U.S. waters; or
2. Foreign-flagged cruise ships currently operating outside of U.S. waters but planning to return to operation in

international, interstate, or intrastate waterways subject to the jurisdiction of the United States; or

3. U.S.-flagged cruise ships choosing to participate in CDC's COVID-19 Program for Cruise Ships.

Status of ships is contingent upon daily submission of the EDC form. When a cruise ship notifies CDC of suspected or confirmed cases of COVID-19 on board, CDC determines whether an investigation is needed based on a predetermined threshold. If an investigation is deemed necessary, CDC will solicit extra information from the cruise ship operator to determine what public health interventions may be necessary. This investigation gives CDC and the cruise industry the ability to work closely together to protect the health and safety of those on board and in communities.

COVID-19 Testing Capabilities

As part of CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters, the purpose of testing is to quickly identify cases of COVID-19—and test and quarantine their close contacts who are not fully vaccinated—to prevent ongoing transmission between voyages. Cruise ship operators participating in the program must have onboard testing capabilities to test all symptomatic crew and passengers for COVID-19 and their close contacts. This includes having onboard rapid nucleic acid amplification test (NAAT) and antigen point-of-care equipment that meets the requirements specified by CDC in technical instructions (e.g., authorized by FDA for use in a CLIA-waived setting); however,

CDC will no longer need to pre-approve these tests. Instead, CDC will verify the cruise ship operator's COVID-19 testing capabilities during routine cruise ship inspections.

For the program's mass crew (and passenger, if applicable) testing requirement, cruise ship operators may use an onboard viral test (NAAT or antigen test) or arrange shoreside testing at a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory so long as it meets the requirements specified by CDC in its technical instructions. Additionally, cruise ship operators must have onboard viral tests for routine crew screening testing. Note, CDC will no longer need to pre-approve these tests. Cruise ship operators may contact CDC to request a list of acceptable NAAT and antigen tests.

Port Agreements

A cruise ship operator that chooses to participate in CDC's COVID-19 Program for Cruise Ships in U.S. Waters must document the approval of all U.S. port and local health authorities where their ships intend to dock or make port during one or more passenger voyages. The agreement must include a port operations component, a medical care plan component, and a housing component meeting the requirements of CDC's technical instructions. Note, cruise ship operators will not need to produce signed contracts between medical and housing facilities when submitting their port agreements. Cruise lines/brands may submit these agreements for all the ships in their fleet.

In lieu of documenting the approval of all local health authorities of jurisdiction, the cruise ship operator may instead submit to CDC a signed statement from a local health authority, on the health authority's official letterhead, indicating that the health authority has declined to participate in deliberations and/or sign the port agreement, i.e., a "Statement of Non-Participation." The cruise ship operator can submit to CDC documentation of attempted communication with the local health authority regarding the port agreement if a response is not received or if the local health authority declines to provide a signed statement. Additionally, the cruise ship operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement.

During discussions with cruise ship operators, port authorities, and state and local health authorities, all parties requested CDC assistance with the required agreements. In response to these requests, CDC has created specific guidance for additional reference.

Inspections

Cruise ships participating in CDC's program are subject to in-person inspections by CDC inspectors. The cruise ship operator's properties and records must be made available for inspection to allow CDC to ascertain compliance with its requirements. Such properties and records include but are not limited to vessels,

facilities, vehicles, equipment, communications, manifests, list of passengers, laboratory test results, and employee and passenger health records. CDC has issued additional technical guidance outlining the specific areas that may be inspected and corresponding recommendations.

CDC has provided, and will continue to provide as necessary, the technical instructions for the COVID-19 Program for Cruise Ships. CDC will work closely with cruise industry, state, territorial, and local health authorities, and seaport partners to evaluate the program components no later than March 18, 2022, and update them as needed. The evaluation will include a review of all public health recommendations and guidance issued as part of the program based on public health conditions and available scientific evidence.

CDC requests OMB approval for an estimated 17,532 annual burden hours.

Estimated Annualized Burden Hours:

Type of Respondent	Form or Information Collection Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)
Cruise ship brand/operator	COVID-19 Program for Cruise Ships Notice of Participation/Nonparticipation	20	1	300/60
Cruise ship brand/operator	Cruise Ship Vaccination Status Classification	130	1	5/60
Cruise ship parent company	COVID-19 Response Plan	3	1	2400/60

Cruise ship physician	Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (Daily)	130	365	20/60
Cruise ship physician	Cruise COVID-19 Case Investigation Worksheet (if necessary)	104	1	30/60
Cruise ship physician	Cruise COVID-19 Contact Investigation Worksheet (if necessary)	24	1	30/60
Cruise ship brand/operator	Agreement with Health Care Organization with signoff from Local Health Authorities	30	1	600/60
Cruise ship brand/operator	Agreement with Port of Entry with signoff from Local Health Authority	30	1	600/60
Cruise ship brand/operator	Agreement with Housing Facility with signoff from Local Health Authority	30	1	600/60
Cruise ship operator	Inspections	130	2	120/60

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